

MEDICAL LABORATORY BOARD MINUTES

Date: April 14, 2005

Time: 9:00 a.m., CDT

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Kelly S. Terry, MT Chairman
Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
Edward McDonald, MD
Thomasa Cooper, Medical Technologist
Norman Crowe, Independent Laboratory Manager/Representative
Yvonne Davis, Medical Technologist
Martha Duncan, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald-Spakes, Cytotechnologist
Delores Voigt, MT Hospital Administrator

Members Absent: Monya Faye Pryor, Citizen Representative

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Health Related Boards Director
Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Brandi Bozarth, Litigating Attorney
Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Staff Absent:

Quorum: A sufficient number of board members were present to constitute a quorum.

Presiding Officer: The meeting was called to order by Chairman, Kelly S. Terry at 9:04 a.m. Board Members introduced themselves to the audience.

Recognition & Welcome: Ms. Terry welcomed the guests and visitors to the board meeting.

Introduction of New Board Members:

Ms. Terry introduced the newly appointed members of the board:

Mr. Norman Crowe appointed to represent the managers/administrators of independent laboratories.

Ms. Yvonne Davis, M.T., appointed to represent the licensure category medical technologist.

Board Minutes: A motion to approve the January 13, 2005 board minutes was made by Ms Voit.

Second: Dr. McDonald.

Approved.

A motion to approve the Committee minutes from the January 12, 2005 meeting was made by Ms Voit.

Second: Dr. McDonald.

Approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of the actions of the Personnel & Education Committee meeting held on April 13, 2005.

Motion to accept this report: Dr. Ferguson.

Second: Dr. McDonald.

Approved.

Board Report-Tennessee Professional Peer Assistance Program:

Mike Harkreader, MA, RN
TNPAP State Director

Mr. Harkreader gave the report from this advocacy agency concerning medical laboratory professionals. A total of 28 licensees have utilized this program since the beginning of the contract period, July 1, 1999.

There was one (1) active participant and one (1) intake participant with one (1) referral from an employer. There were two (2) individuals that were reported to the Department that refused participation in this program.

Motion: Dr. Ferguson.

Second: Ms. Duncan.

Approved.

A copy of Mr. Harkreader's report is on file in the board's administrative office.

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held March 24, 2005 concerning the following amendments to:

1- Rule 1200-6-1-.05 criminal background checks for new licensees.

2- Rule 1200-6-3-.01; 1200-6-3-.09 regarding board approved certification agency name change.

3- Rule 1200-6-3-.16 regarding alternate site testing for screening programs.

There were no comments during the rulemaking hearing to these proposed rule changes.

Motion to accept the changes was made by Mr. Crowe.

Second: Ms. Lahr.

A roll call vote was taken with all members present voting aye.

B. Authorize Rulemaking Hearing:

The board authorized a rulemaking hearing to be held July 8, 2005 for:

1-Rule 1200-6-1-.20(5)(e)15 Qualifications & Duties of the Medical Laboratory Director.

2-Rule 1200-6-1.21 (2)(b) Qualifications & Duties of the Medical Laboratory Supervisor.

3-Rule 1200-6-3-.09(8) Quality Control-Control Procedures.

4-Rule 1200-6-3-.12(1)(o) Referral of Cultures to the Department of Health.

5-Rule 1200-6-3-.16(1)(c)(5) Alternate Site Testing.

Ms. Faye Abdulla, represented the state's Laboratory Services Division working in conjunction with the State Epidemiologist, spoke of the importance of referring communicable disease isolates (microbiological organisms) to the Department. The request was for the addition of three (3) organisms that are considered potential bioterrorism threats and two (2) organisms that are considered emerging pathogens. (Item 4).

These organisms are:

Escherichia coli O157:H7

Bacillus anthracis

Burkholderia mallei

Burkholderia pseudomallei

Vancomycin resistant staphylococcus aureus (VRSA)

Vancomycin intermediate staphylococcus aureus (VISA)

A motion to authorize a rulemaking hearing for Items 1-5 was made by Dr. Ferguson.

Second: Ms. Cooper.

Approved.

Contested Case:

There were no contested cases during this meeting.

Agreed Orders:

Brandi Bozarth

Assistant General Counsel

Susan S. Berry

MT #2110

Formal Reprimand

A motion to ratify this reprimand was made by Dr. McDonald.

Second: Ms. Lahr.

Approved.

Theresa J. Smith

MT #2793

Formal Reprimand

A motion to ratify this reprimand was made by Dr. McDonald.

Second: Ms. McDonald-Spakes.

Approved.

Bruce A. Lewis

MT # 18717

Letter of Concern

A motion to reject the agreed order in favor of a letter of concern sent to Mr. Lewis was made by Dr. Ferguson.

Second: Dr. Carter.

Approved.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).

2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)

Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, contact with TNPAP for peer assistance services, legislative actions, website updates, and facility closures.

Motion: Ms. Voit.

Second: Ms. McDonald Spakes.

Report Approved.

The complete report is on file in the board's administrative office.

Direct More Than Three (3) Labs

Rule 1200-6-3-.13(5) Medical Lab Facilities:

No requests were presented to the board on this subject during the April meeting.

Reinstatement of License:

There were no requests for licenses to be reinstated during this meeting.

Reports/Discussion:

Reports:

Regional Consultant/Surveyor – Proficiency Testing (PT) & Complaint Investigations/Licensed Laboratory Facilities

East Tennessee Regional Office-Julia Daniels, Consultant II/Surveyor; Onezean Otey, Jr., Consultant I/Surveyor

Ms. Daniels gave the report:

Unsatisfactory/ Unsuccessful Proficiency Testing:

Proficiency testing issues were addressed with three (3) licensed facilities to include the first unsuccessful participation for the following:

PTT-incorrect reagent code and/or did not complete PT reporting form.

HCT-random error with quality control and quality assurance records/no patient results affected.

Parasitology-testing discontinued due to low volume with no patients reported during the cycles proficiency testing was performed.

Complaint Investigations: There was zero (0) investigations during the last quarter of 2005.

Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor; Irmgard A. Brown, Consultant I/Surveyor

Ms. Bogard gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is two (2):

Laboratory #1: Unsuccessful PT for Na, Fib and ETOH.

Laboratory #2: Unsuccessful PT for blood parasites.

The number of state licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events (three out of four/three in a row): zero (0).

Complaints Investigations:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigations during this quarter.

West Tennessee Regional Office-Mary J. Hamblen, Consultant II/ Surveyor; Karen Daniels, Consultant I/Surveyor

Ms. Daniels gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): two (2).

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

Motion: Dr. McDonald.

Second: Ms. Davis.

Report Approved.

Discussion:

Ms. Hamblen requested clarification of quality control (QC) frequency, Rule 1200-6-3.09, pertaining to the operation of a random access analyzer (Beckman, LX20, CX9 and Access). There is no calibration done less frequently than twenty-four (24) hours and routine maintenance is performed one time a day per manufacturer's recommendation. QC interval is at least two (2) levels of control material analyzed on a daily basis.

Is it possible to consider a "run" on as the twenty-four (24) hour period between the times that daily maintenance is performed since the instrument can run on a continuous basis during that time?

Would it be necessary to repeat quality control (QC) if no reagents are added or no extra maintenance (troubleshooting measures) during this period? Is calibration is required during the twenty-four (24) hour period is it necessary to repeat QC?

The consensus of the Board was that two (2) levels of control per twenty-four(24) yours would suffice under these circumstances as long as the reportable dimensions of the instrument are in range.

Richard Mullins, Ph.D.
Director, Clinical Pharmacokinetics Laboratory
Pharmaceutical Sciences Dept.
St. Jude Children's Research Hospital
Memphis, TN 38015

Dr. Mullins appeared before the board to request the consideration of the American Board of Clinical Chemistry, specialty Molecular Diagnostics, (ABCC/MD), as an acceptable boarding for a Ph.D. to direct a molecular diagnostics laboratory.

Motion: To approve this credentialing agency and the category as a pathway for director molecular pathology was made by Dr. McDonald.

Second: Ms. Lahr.

Approved.

Ms. Cooper recused herself from the discussion and vote.

Mr. George W. Lobdell, M.P.H.
Director
Office of Cancer Surveillance

Ms. Becky Jones

Mr. Lobdell and Ms. Jones appeared before the board to request the authorization of a rule making hearing for new language in rules regarding the reporting pathology diagnosed in laboratory facilities per TCR 68-1-1002 to the Tennessee Cancer Registry (TCR). This agency requested an amendment to the medical laboratory facility rules to incorporate the reporting of lab results to the TCR.

After a board discussion, it was determined this Board did not have authority to enforce this rule for reporting results to the TCR. The administrative office volunteered to assist with providing documentation from this state agency to the laboratory facility by including this request in general facility correspondence.

Health Related Board's Report/Discussion:

Robbie Bell, Director

Ms. Bell did not make a report to the board during this meeting.

Office of General Counsel Report:

Robert J. Kraemer, Jr.

Advisory Attorney

Mr. Kraemer led the discussion of the following items:

Temporary Permits & Cleanup (04-1037) The rulemaking hearing was held on March 19, 2004; this amendment was adopted by the Board on April 15, 2004 and was sent to the Attorney General on April 22, 2004. The amendment was signed by the Attorney General and filed with the Secretary of State on October 22, 2004 and became **2004 effective December 25, 2004.**

Hematology Controls (04-1192) The rulemaking hearing was held on July 8, 2004 and the Board adopted the amendment on July 15, 2004. These rules were filed with the Attorney General on July 21, 2004 and went to the Secretary of State on January 14, 2005 and became **effective March 30, 2005.**

Screening Tests and Civil Penalties (04-1378) The rulemaking hearing was held on September 23, 2004 and this amendment was adopted by the Board on October 14, 2004. The amendment was sent to the Attorney General on January 27, 2004 and is still there.

Continuing Education, Temporary Licensure & Lab Test Orders (04-1554) The rulemaking hearing was held on December 17, 2004 and these amendments were adopted by the Board on January 14, 2005. These amendments were sent to the Attorney General on January 18, 2005 and are still there.

Criminal Background Checks & Screenings (05-1026) The rulemaking hearing was held on March 24, 2005 after response to comments, these amendments are ready for adoption at this meeting.

Litigation:

The Office of General Counsel currently has seven (7) open disciplinary cases pertaining to the Medical Laboratory Board.

Motion: Mr. Crowe.

Second: Ms. Davis.

Report Approved.

Bureau of Investigations (BIV) Report:

There are three (3) open complaints in BIV which were carried over from December 2004. There have been no new complaints filed during this quarter. A report of previous disciplinary actions on licensed personnel was also included in each board book.

Motion: Ms. Duncan.
Second: Dr. McDonald.
Report Approved.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is on file in the administrative office.

Waived Testing Procedures:

There were no additions or deletions made to the waive test lists.

Point of Care Task Force:

This task force asked for the administrative office to consider putting the board point of care grid on the internet. Ms. England stated she would work on this request.

Review Eligibility of Medical Laboratory Director:

Kristin May, Ph.D.
Stone Mountain, GA
Director-Cytogenetics

Ms. Thacker informed the Board Dr. May's file was complete and she has met the requirements for licensure in the category of Director of Cytogenetics. The applicant holds a Ph.D. degree in the specialty of human genetics and is boarded by the American Board of Medical Genetics as a Clinical Cytogeneticist.

Motion: Dr. McDonald.
Second: Ms. Duncan.

Approved.

Oristyne E. Walker, Ph.D.*
Jackson, TN
Director-Diagnostic Immunology

Ms. Thacker informed the Board Dr. Walker holds a Ph.D. in Biology/Microbiology and is boarded by the American Board of Bioanalysis in the category of Diagnostic Immunology.

Motion: Dr. McDonald
Second: Ms. Duncan
Approved.

*Contingent on Florida providing documentation of negative disciplinary problems while she was licensed in that state.

Other Business:

The meeting was briefly adjourned at 1:25 pm CDT to discuss business associated with the Personnel & Education Committee on a motion by Ms. Voigt and seconded by Dr. Ferguson.

The full board meeting resumed discussion at 1:35 pm CDT.

Statement of Next Meeting:

The next meeting will be held on July 14, 2005 beginning at 9 am, CDT in the Cumberland Room, Ground Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment:

Motion: Ms. Duncan.
Second: Ms. McDonald-Spakes.
Approved.

The meeting adjourned at 2:30 pm CDT.

Kelly S. Terry, MT
Board Chairman

Date

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. Baptist Memorial Hospital-Memphis
6019 Walnut Grove Road
Memphis, TN 38120

Facility Representative: Lynda Meyer, BS, MT(ASCP)
Administrative Director Pathology

This facility request was for Registered Nurses (RN's) to perform and report sodium, and hematocrit in the Emergency Department utilizing the i-STAT instrument and methodologies.

Motion: Dr. McDonald.
Second: Ms. Cooper
Approved.

2. Parkridge Medical Center
2333 McCallie Avenue
Chattanooga, TN 37404

Facility Representative: Sheila Hilley, MT(ASCP)
Laboratory Manager

This request was for Clinical Licensed Perfusionists to perform and report sodium, potassium, chloride, glucose, PO₂, PCO₂, pH and calculated hemoglobin in the Open Heart Suites during cardiopulmonary bypass surgery. The instrument of choice is the Osmetech OPTI CCA.

Motion: Dr. McDonald
Second: Dr. Ferguson.
Approved.

3. Wellmont Hancock County Hospital Laboratory
1519 Main Street Highway 33
Sneedville, TN 37869

Facility Representative: Ed Bush, Brenda Mosby
Laboratory Administration

Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
April 14, 2005

This facility made the following exemption requests:

1- Licensed Nurses (RN's & LPN's), Respiratory Therapists & Radiology Technicians to perform and report ionized calcium, sodium, potassium, glucose, lactate, hematocrit, pH, pCO₂ & pO₂ in the Emergency Department and Medical Unit utilizing the GEM 3000 instrument and methodologies.

Motion: Dr. Carter
Second: Dr. McDonald.
Approved.

2-Licensed Nurses (RN's & LPN's), Respiratory Therapists & Radiology Technicians to perform and report troponin analyses on the i-STAT instrument in the Emergency Department and Medical Unit.

Motion: Dr. McDonald
Second: Dr. Carter.
Approved.

3-Licensed Nurses (RN's & LPN's), Respiratory Therapists & Radiology Technicians to perform and report BNP in the Emergency Department and Medical Unit utilizing the Biosite Triage Panel.

Motion: Dr. McDonald
Second: Dr. Carter.
Approved.

4-Licensed Nurses (RN's & LPN's), Respiratory Therapists & Radiology Technicians to perform a and report creatinine on the i-STAT instrument in the Emergency Room and Medical Unit utilizing the i-STAT instrument.

Motion: Dr. McDonald
Second: Dr. Carter
Approved.

5-Licensed Nurses (RN's & LPN's), Respiratory Therapists & Radiology Technicians to perform and report drugs of abuse, PCP, benzodiazepine, cocaine, amphetamine, THC, opiates, barbiturates and TCA on the Biosite Triage Panel in the Emergency Department and Medical Unit.

Point of Care Exemption Requests
April 14, 2005

Motion: Dr. McDonald
Second: Ms. Davis
Approved.

7-Licensed Nurses (RN's & LPN's), Respiratory Therapists & Radiology Technicians to perform and report mononucleosis testing procedures in the Emergency Department and Medical Unit.

The procedure utilized is the QuickVue+ Infectious Mononucleosis Test System.

Motion: Dr. McDonald
Second: Ms. Davis
Approved.

The board **denied** the request for these same health care professionals to perform and report cardiac markers, troponin, myoglobin and CK-MB in the Emergency Department and Medical Unit utilizing the Biosite Triage Panel.

The board requested a follow-up evaluation report on these approved requests during the quarterly meeting, October 13, 2004.

4. Maury Regional Hospital Laboratory
1224 Trotwood Avenue
Columbia, TN 38401

Facility Representative: Amy Bridges, MT
Point of Care Coordinator

This request was for Registered Nurses (RN's), Licensed Practical Nurses (LPN's), and Certified Respiratory Nurse Anesthetists (CRNA's) to perform and report blood gases, electrolytes, glucose, BUN, creatinine, hematocrit and ionized calcium in the Operative Areas of Surgery, Anesthesia and Recovery. The instrument of choice is i-STAT System 1.

Motion: Dr. McDonald.
Second: Dr. Ferguson.
Approved.

Attachment 2
Initial Facility Licenses
Medical Laboratory Board
April 14, 2005

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION:

Lifeblood/Mid-South Regional Blood Center

501 University Street Suite 201
Memphis, TN 38152

Medical Laboratory Director: Edward Scott, M.D.
American Board of Pathology-Blood Bank

Specialties: Spun Hematocrit/Blood Donor Center

Surveyor: Mary J. Hamblen, MT Consultant II/Surveyor
West TN Regional Office

Motion: Dr. Ferguson
Second: Dr. Carter
Approved.

Wellmont Hawkins County Memorial Hospital-Point of Care

851 Locust Street
Rogersville, TN 37857

Medical Laboratory Director: Paul Sides, Jr., M.D.
American Board of Pathology
Anatomic & Clinical

Specialties: TN Medical Laboratory Board Waived and/or Exempted Point of
Care Tests

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald
Second: Dr. Carter.
Motion: Approved *

Wellmont Holston Valley Medical Center-Point of Care
130 West Ravine Road
Kingsport, TN 37660

Medical Laboratory Director: Gary Adelson, M.D.
American Board of Pathology
Anatomic and Clinical

Specialties: TN Medical Laboratory Board Waived and/or Exempted Point
of Care Tests, Arterial Blood Gases & pH , O2 Saturations,
and Activated Clotting Times.

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald
Second: Mr. Crowe.
Approved. *

Wellmont Bristol Regional Medical Center-Point of Care
1 Medical Park Blvd. Suite G-50
Bristol, TN 37620

Medical Laboratory Director: Jack Bechtel, Jr., M.D.
American Board of Pathology
Anatomic and Clinical

Specialties: TN Medical Laboratory Board Waived and/or Exempted Point
of Care Tests, Arterial Blood Gases and pH, O2 Saturations,
and Activated Clotting Time

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald*
Second: Ms. Voit
Approved.

* Dr. Ferguson recused himself from the discussion and vote.

St. Mary's North
7551 Dannaher Lane
Powell, TN 37849

Medical Laboratory Director: Frank J. Beuerlein, M.D.
American Board of Pathology
Anatomic & Clinical

Specialties: Hematology

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald
Second: Dr. Ferguson.
Approved.

Spectrum TN Network-Tri City Stat Laboratory
2025 Meadowview Parkway
Kingsport, TN 37660

Medical Laboratory Director: Gary L. Adelson, M.D.
American Board of Pathology
Anatomic & Clinical

Specialties: Hematology, Diagnostic Immunology, Clinical Chemistry,
Urinalysis, Toxicology

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald *
Second: Ms. Duncan
Approved.

* Dr. Ferguson recused himself from the discussion and vote.

Cookeville Medical Center, PC

225 North Willow Avenue
Cookeville, TN 38501

Medical Laboratory Director: R. Samuel Kincaid, M.D.
American Board of Pathology
Anatomic & Clinical

Specialties: Hematology, Diagnostic Immunology, Clinical Chemistry,
Urinalysis, Endocrinology, Toxicology, H. pylori Screen,
Influenza Screen, KOH, Wet Prep, Strep A Antigen Screen

Surveyor: Sandra S. Bogard, Consultant II/Surveyor
Middle TN Regional Office

Motion: Dr. Ferguson
Second: Ms. McDonald-Spakes
Approved.

Quest Diagnostics Laboratory

412 Railroad Street
Elizabethton, TN 37463

Medical Laboratory Director: Susan Rollins, M.D.
American Board of Pathology
Anatomic & Clinical

Specialty: Collection Station

Surveyor: Julia Daniels, Consultant II, Surveyor
East TN Regional Office

Motion: Ms. Voigt
Second: Ms. Davis
Approved.

Wellmont Health System, Medical Park Blood Center

1 Medical Park Blvd., Suite G-50
Bristol, TN 37620

Medical Laboratory Director: Jack T. Bechtel, Jr., M.D.

American Board of Pathology
Anatomic & Clinical

Specialties: Blood Donor Center, General Immunology

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald
Second: Ms. Duncan
Approved.

Wellmont Hancock County Hospital
1519 Main Street Hwy 33
Sneedville, TN 37869

Medical Laboratory Director: Paul J. Sides, Jr., M.D.
American Board of Pathology
Anatomic & Clinical

Specialties: Bacteriology, Virology, Hematology, General Immunology,
Clinical
Chemistry, Urinalysis, Toxicology, Arterial Blood Gases & pH,
Gram's Stain

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. McDonald*
Second: Mr. Crowe
Approved.

* Dr. Ferguson recused himself from the discussion and vote.

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